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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,947	09/12/2003	Charles Eric Mowbray	PC25375A	8400

28940 7590 04/28/2005

AGOURON PHARMACEUTICALS, INC.
10350 NORTH TORREY PINES ROAD
LA JOLLA, CA 92037

EXAMINER

GRAZIER, NYEEMAH A

ART UNIT PAPER NUMBER

1626

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,947

Applicant(s)

MOWBRAY ET AL.

Examiner

Nyeemah Grazier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/13/2004.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

ACTION SUMMARY

Claims 1-19 are currently pending this application. Examiner withdraws **Claims 9-18** from further consideration because said claims are drawn to non-elected inventions. 37 C.F.R. 1.142(b).

Further, **Claims 1-8 and 19** are rejected because the instant invention as recited is not identically disclosed in the references cited by the Applicant, however the difference between the instant invention and the prior art renders the instant invention obvious under 35 U.S.C. § 103(a).

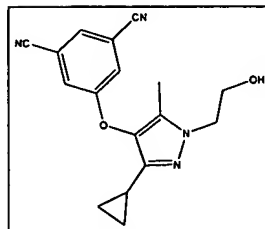
PRIORITY

The instant application claims benefit of US Application Serial No. 60/433,397 filed on December 13, 2002. The instant application also claims benefit to the earliest filing date of foreign application UK 0221477.3 filed on September 16, 2002.

ELECTION/RESTRICTIONS

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 –8, and 19, drawn to a compound of Formula (1), classified in class 548, and subclass 369.4.



Formula (I)

- II. Claims 9 - 10, drawn to a method of treating HIV, acquired immune deficiency syndrome (AIDS) or a genetically related retroviral infection, classified in class 514, subclass 407.
- III. Claims 11 - 12, drawn to a process for preparing the compound of Formula (I), classified in class 548, subclass 369.4.
- IV. Claims 13 - 18, drawn to an intermediate compound of Formula (I) classified in class 558, subclass 423.

The inventions are distinct, each from the other for the following reasons: Invention I is distinct from Inventions II, III, and IV because Invention I is drawn to a compound of Formula I or composition thereof while Inventions II and III are drawn to a different statutory subject matter. Invention I is distinct from Invention IV because although they are both drawn to a compound, the compound claimed in Invention IV is an intermediate and are classified in different classes and/or subclasses. Invention II is distinct from Invention III is because II is drawn a different statutory subject matter, namely a method of treatment and III is drawn another statutory subject matter, namely a process of making compound of formula (I). Lastly, Invention IV is distinct from Invention II and III because they are each drawn to different statutory subject matter, specifically, IV is drawn to a compound, II is drawn to a method of treatment and III is drawn to a process of making.

The inventions require different search requirements as they are drawn to either different statutory subject matter or different classification categories. Therefore, a search of the inventions without the abovementioned restrictions is burdensome. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Advisory of Rejoinder

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims, which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final

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rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations** of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Pursuant to M.P.E.P. § 821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed

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product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Telephone Inquiry/Election

It should be noted that during a telephone conversation with Keith J. Hutchinson, Esquire on April 7, 2005 a provisional election was made with traverse to prosecute the invention of Group I, Claims 1 – 8, and 19. It is noted that Mr. Hutchinson also requested that the Office consider Group II for rejoinder should there be evidence that the product and process are free of art. Applicant in replying to this Office action must make affirmation of this election. Claims 9 - 18 are hereby withdrawn from further consideration by the examiner as being drawn to a non-elected invention pursuant to 37 CFR 1.142(b).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the named inventors is no longer an inventor of at least one claim remaining in the application.

Amendments of inventorship must be accompanied by a request under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

A. FORMALITY OBJECTIONS

OBJECTION TO THE SPECIFICATION: Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract as written contains two paragraphs. Correction is required. See MPEP § 608.01(b).

B. STATUTORY REJECTIONS

I. CLAIM REJECTIONS 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

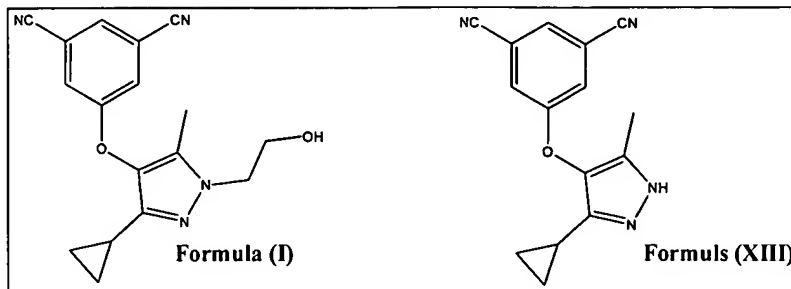
Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Corbau et al, WO 02/004424 A1 (hereinafter referred to as “the WO ‘424 publication”) in view of Jones et al, WO 02/085860 A1 (hereinafter referred to a “the WO ‘860 publication”).

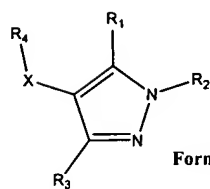
First, Instant **Claim 1** recites a compound of Formula (I) or a pharmaceutically acceptable salt, solvate or derivative thereof. Next, **Claim 3, 5, and 7** recite “a compound according to claim 1” wherein the compound claims an intended use. Lastly, **Claim 19** recites a compound of Formula (XIII). The following are structures of Formula (I) and (XIII) as described in the instant application.

Furthermore, **Claim 2** recites “[A] pharmaceutical composition comprising the compound according to claim 1 and one or more pharmaceutically acceptable excipients, diluents or carriers.” **Claims 4, 6 and 8** depend from Claim2 wherein the invention as recited is “a composition according to Claim 2” for a specified intended use.



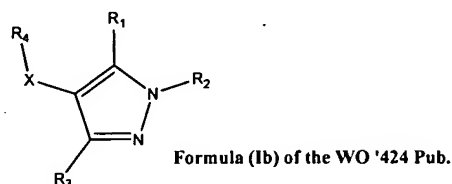
(1) Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The WO '424 publication teaches a the compound of Formula (I),



wherein X is sulfur, R₁ is methyl, R₂ can be ethyl alcohol, R₂ can also be hydrogen, R₃ is cyclopentyl, and R₄ is 3,5-dicyanophenyl to afford a compound inherently similar to the Formula (I) of the instant invention. (See e.g., Corbau, et al, WO 02/004424 A1, p. 155, l.10; p. 153, l. 7; p. 157, l. 29; p. 153, l. 14; p. 153, l. 26; and p. 12, l. 23 respectively.)

Furthermore, WO '424 also teaches “a pharmaceutically composition including a compound of Formula (Ib) or a pharmaceutically acceptable salt or solvate thereof, together with a pharmaceutically acceptable excipient, diluents or carrier.” *Id.* at 39, ll. 1-3.



The substitutions on Formula (Ib) are identical to the instant invention, Formula (I) with the exception of the oxygen linker; wherein X is sulfur, R₁ is methyl, R₂ can be ethyl alcohol, R₃ is cyclopentyl, and R₄ is 3,5-dicyanophenyl to afford a compound inherently similar to the

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Formula (I) of the instant invention. (See e.g., Corbau et al, WO 02/004424 A1, p. 6, l. 29; p. 4, l. 15; p.10, l. 25; p.4, l. 29; p. 13, ll. 6-7 respectively.)

(2) Ascertainment of the Difference Between the Prior Art and the Claims (MPEP §2141.02)

The single difference between the prior art of the WO '424 publication and the instantly claimed inventions is that the invention disclosed in the WO '424 publication claims comprises (3,5 dicyanophenyl) sulfonyl substitution at the four position on the pyrazole moiety. Thus, the instant inventions are distinguishable merely because it comprises 3,5 dicyanophenoxy at the four position o the pyrazole ring. See Corbau et al, WO 02/004424A1, p. 153, ll. 7 (R1=CH3), 26 (R3 = cyclopropyl); p. 155, l. 10 (X = sulfur); p. 154, l. 6 (R4=substituted phenyl); and p. 157, l.29 (R2=-CH2CH2OH), for example.

However, the WO '860 publication teaches the benefit of using a disubstituted phenoxy at the four position on the pyrazole ring. See Jones et al, WO 02/085860 A1, p. 154, Ex. 195, p. 152, Ex. 193, for example).

(3) Finding of Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

The WO'424 publication is comparable to the instant invention in view of the WO '860 publication because the compounds of the instant claims are substantially similar to the compounds disclosed in the WO'424 publication. The only difference is the oxygen rather than a sulfur. The instant invention recites that the same core structure and substantially the same key substitutions of the substituent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to synthesis a compound of Formula (I) where "X" is oxygen and sulfur because the elements have similar properties as they are both in Group VIIA

of the Periodic Table. More importantly, WO'860 in view of the WO '424 teaches the benefit of using phenoxy and the phenylsufanyl substitution at the four position on the pyrazole moiety.

The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979). The teaching of the WO'424 publication together with the instant invention as recited in Claims 1, 3, 5, 7 and 19 of the instant application would have motivated one skilled in the art to modify the reagents in the instant application with the teaching of the WO '424 publication in view of the WO '860 publication to make compounds with sulfur and oxygen independently, with the expectation that they would both have the same properties and activity.

OBJECTIONS TO THE CLAIMS

Claims 3, 5 and 7 are objected to pursuant to 37 CFR 1.75 as being a substantial duplicate of Claim 1. **Claims 4, 6, and 8** are also objected to under 37 CFR 1.75 as being a substantial duplicate of Claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the instant case Claims 3, 5, and 7 and Claims 4, 6, and 8 claim respectively, the compound and the composition of the compound as the invention. The intended use of the invention, such as "for use as a medicament" (See Instant Claim 3) is given no patentable weight. It is therefore apparent that the claims as recited are substantial duplicates.

For example, instant Claim 3 recites “[A] compound according to claim 1 for use as a medicament.” If however, in instant Claim 3, for example, applicant is claiming a method of use for the compound of Formula (I) for the use as a medicament, then Applicant must amend the claims. Applicant is advised that should Applicant amend the abovementioned claims the disclosure, as originally filed, must provide support. 37 C.F.R. 1.48(c).

CONCLUSION

The Examiner withdraws **Claims 9-18** from further consideration because Claims 9-18 are drawn to a non-elected invention. 37 C.F.R. § 1.142(b). **Claims 1-8 and 19** are rejected to under 35 U.S.C. § 103. Lastly, **Claims 3-8** are objected to as duplicate claims.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The Examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

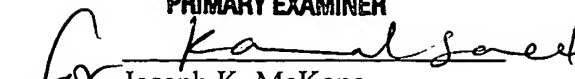
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Very truly yours,


Nyeemah Grazier

Patent Examiner, AU 1626
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Remsen Building, 5B29
Alexandria, VA 22314-5774
Tel.: (571) 272-8781

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER


for Joseph K. McKane
Supervisory Primary Examiner, AU 1626

DATED: April 26, 2005